

PATENTS
CUSTOMER NO. 29052
ATTY. DOCKET NO. 23578-0007



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Zatezalo et al.)
Serial No. 09/941,224) Art Unit: 3737
(continuation application of the)
U.S. Patent No. 6,339,718) Examiner: William C. Jung
Filed: August 28, 2001)
For: Apparatus and Method for Programming)
a KVO Phase and a First Phase of an)
Injection Procedure as Flushing Medium)
Phase)

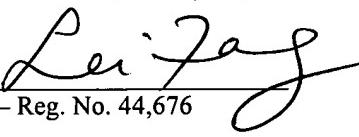
**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.56
AND NOTICE OF RELATED LITIGATION UNDER 37 CFR 1.178**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement and Notice of Related Litigation are filed in accordance with 37 CFR §1.56, §1.97, §1.98 and §1.178. Applicants herewith disclose references and call to the attention of the Examiner the pending federal court litigation relating to U.S. Patent No. 6,339,718 ("the '718 patent"), a parent patent of the above-identified continuation application.

I hereby certify that this correspondence is being deposited with the United States Postal Service via Express Mail, Express Mail Mailing Label No. EL 973738335 US, addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 25, 2005.


Lei Fang – Reg. No. 44,676

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Serial No.: 09/941,224
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IDS & Notice of Litigation

Applicants respectfully submit that the references and any litigation related documents and/or materials are made of record to assist the Examiner in the examination of the above-identified continuation application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teachings and relevance to this application.

Notice of Pending Litigation Related to the ‘718 patent: MPEP 2001.06 (c)

1. *Medrad, Inc. v. Tyco Healthcare Group, LP, et al.*, Civil Case No. 01-1997-DEC, U.S.D.C. (W.D. Penn.) (“the Pennsylvania litigation”)

The litigation documents exchanged by the parties of this Pennsylvania litigation were listed on the Form PTO-1449 and previously submitted to the Examiner on June 2, 2003. In addition, on August 11, 2003, Medrad executed a Covenant indicating that the parties are desirous of dismissing the portions of the Pennsylvania litigation relating to the ‘718 patent. The Covenant stated that Medrad did “not to sue and forever release” Tyco et al. from any and all claims “solely relating to infringement of … the ‘718 patent based on the manufacturing, use, sale and/or offer for sale of Optistar MR Injector Systems that are or have been publicly available for purchase in the United States as of the date hereof.” A citation of the Covenant is listed on the attached new Form PTO-1449 and a copy of the Covenant is also enclosed herewith.

2. *Tyco Healthcare Group LP, et al. v. Medrad, Inc.*, Civil Case No. 04-773, U.S.D.C. (S.D. Ohio) (“the Ohio litigation”)

Applicants hereby notify the Examiner that the ‘718 patent, as well as the U.S. Patent No. 6,643,537 (“the ‘537 patent”), has also been involved in the Ohio litigation instituted by Tyco Healthcare Group LP (“Tyco”), Mallinckrodt Inc. (“Mallinckrodt”) and Liebel-Flarsheim Company (“L-F”), against Medrad for Declaratory Judgment. This Ohio litigation was filed in the United States District Court for the Southern District of Ohio on November 15, 2004, under Civil Case No. 04-773.

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In the Ohio litigation, Tyco et al. alleged that the '718 patent is invalid, unenforceable and the claims of the '718 are not infringed (*See* Tyco et al.'s Complaint of November 15, 2004, Background Facts, pages 4-6; First Cause of Action, pages 6-12). Citations of the Tyco et al.'s Complaint, as well as other litigation documents exchanges by Tyco et al. and Medrad in the Ohio litigation are listed on the attached new Form PTO-1449, and copies of each document are enclosed herewith.

- 1) Tyco et al.'s Complaint for Declaratory Judgment and Jury Demand dated November 15, 2004;
- 2) Medrad's Answer and Counterclaims filed December 28, 2004;
- 3) Tyco's Reply to Defendant's Counterclaims filed January 20, 2005
- 4) Tyco's First Set of Interrogatories Nos. 1-8 to Defendant filed February 7, 2005;
- 5) Tyco's First Set of Requests for Production of Documents to Defendant filed February 7, 2005;
- 6) Medrad's Responses and objections to Plaintiffs' First Set of Requests for Production of Documents to Defendant filed March 11, 2005;
- 7) Medrad's Responses to Plaintiffs' First Set of Interrogatories Nos. 1-8 to Defendant filed March 11, 2005;
- 8) Medrad's First Set of Requests for Production of Documents and Things to Plaintiffs filed March 18, 2005;
- 9) Medrad's First Request for Entry Upon Land and Inspection of Things Thereon to Plaintiffs filed March 18, 2005;
- 10) Medrad's Consent Motion to Amend Answer and Counterclaims filed March 24, 2005;
- 11) Medrad's Amended Answer and Counterclaims filed March 24, 2005;
- 12) Medrad's First Set of Interrogatories (Nos. 1-9) filed March 24, 2005;
- 13) Tyco's Reply to Defendant's Amended Counterclaims filed April 27, 2005;
- 14) Tyco's Response to Medrad's First Set of Requests for Production of Documents and Things filed May 20, 2005; and

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15) Tyco's Response to Medrad's First Set of Interrogatories (Nos. 1-9) filed May 26, 2005.

In Medrad's Answer and Counterclaims to Tyco's Complaint, and later, in Medrad's Amended Answer and Counterclaims to Tyco's Complaint, Medrad modified the "Facts" section of its Counterclaims by referring to the '205 patent, adding a Third Counterclaims alleging infringement of the '205 patent, and modifying Medrad's Prayer for Relief. Validity and infringement allegations relating to the '718 patent are set forth on pages 3-6 and 11-12. However, in Tyco's Reply to Medrad's Counterclaims and Amended Counterclaims, Tyco et al. denied the infringement allegations of Medrad's Counterclaims relating to the '718 patent (page 2, paragraph 9, and page 3, paragraphs 15-18; or page 4, paragraphs 16-19).

In Medrad's Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-8), Medrad objected that the interrogatory was premature in that limited discovery has been done (pages 4, 8, 10, and 11). Medrad further asserted that Medrad's investigation of infringement by Tyco et al. is ongoing but alleged that Plaintiffs' OptiVantage™ DH injection system literally infringes at least claims 24 and 27 in the '718 patent (and claims 6, 19 and 22 in the '537 patent) (pages 4-8). In Medrad's Responses and Objections to Plaintiffs' First Set of Requests for Production of Documents and Things, Medrad objected to each request as being duplicative, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence (General Objections on page 1; and Responses to each Request).

In Tyco's Responses to Medrad's First Set of Requests for Production of Documents and Things, Tyco simply objected each Request to the extent that 1) each Request sought the production of documents or things that are protected by the attorney-client and/or work product privileges; 2) the Requests sought information unrelated to any claim or defense in this action and is likely to lead to the discovery of admissible evidence; and/or 3) the Requests were overly broad and burdensome. In Plaintiffs' Responses to Medrad's First Set of Interrogatories (Nos. 1-9), non- infringement allegations relating to the '718 patent are set forth on page 6 (Response to

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Interrogatory No. 5) with references to the preliminary non-infringement chart attached as Exhibit A. Unpatentability and invalidity allegations, and unenforceability due to inequitable conduct allegations relating to the '718 patent are set forth on pages 6-8 (Response to Interrogatory No. 6); pages 8-9 (Response to Interrogatory No. 7); and pages 9-15 (Response to Interrogatory No. 8). Note that information relating to the '718 patent (as well as to the '537 patent) of alleged prior art, Nemoto Sonic Shot 50 MR injector, the Medrad MR Spectris Injector, the Injektron 82 MRT 1.4 manual, U.S. Patent No. 5,472,403 to Cornacchia, and U.S. Patent No. 5,806,519 to Evans, III were disclosed in numerous documents submitted with the Information Disclosure Statement, and were also considered by the Patent Office during the prosecution of the above-identified continuation application (*See* the First Office Action dated July 30, 2003), as well as during the prosecutions of the '718 patent and the '537 patent, respective (*See, for example*, IDS submitted on November 1, 2000; First Office Action dated December 18, 2000; and IDS submitted on May 17, 2001 during the prosecution of the '718 patent; *see also, for example*, IDS and Notice of Related Litigation submitted on May 19, 2003, and IDS submitted on May 29, 2003 during the prosecution of the '537 patent).

Applicants believe that certain of the alleged prior art references are not or may not be prior art to the application, and therefore reserve the right to assert that one or more of the references is not prior art to this application. Moreover, Applicants believe they can successfully swear behind many, if not all, of the Section 102 (a) and (e) references based on prior conception and/or reduction to practice.

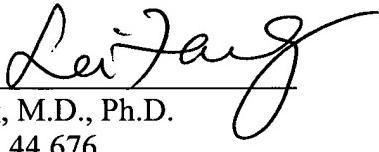
Nevertheless, Applicants would like the Examiner to at least initially consider the subject matter disclosed in the relevant references vis-à-vis the pending claims because Applicants believe the claims will define over the references.

This Information Disclosure Statement is being filed with a Request for Continuation Examination (RCE), no fee is required under 37 C.F.R. 1.17 (p) for consideration of this Information Disclosure Statement. The Examiner is respectfully requested to initial copies of the

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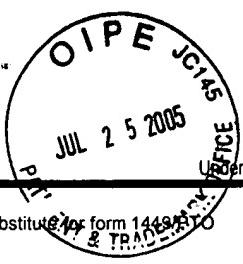
attached Form PTO-1449 to show consideration of the references, and to return the initiated forms to the undersigned counsel.

Respectfully submitted,



Lei Fang, M.D., Ph.D.
Reg. No. 44,676

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Attorney Docket No.: 23578-0007



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				Complete if Known	
				Application Number	09/941,224
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				First Named Inventor	Zatezalo et al.
				Art Unit	3737
				Examiner Name	William C. Jung
Sheet	1	of	2	Attorney Docket Number	23578.0007

U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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***EXAMINER:** Initial if references considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **^**Applicant's unique citation designation number (optional). **^2**See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

⁴Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁵For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁷Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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				Filing Date	August 28, 2001
				First Named Inventor	Zatezalo et al.
				Art Unit	3737
				Examiner Name	William C. Jung
Sheet	2	of	2	Attorney Docket Number	23578.0007

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the articles (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. T ²			
		Injektron 82 MRT Operating Instructions, MR 1.4 Version (October 1997).			
		English Translatin of Injektron 82 MRT Operating Instructions, MR 1.4 Version (October 1997).			
		<i>Medrad, Inc. v. Tyco Healthcare Group, LP et al.</i> , Civil Case No. 01-1997-DEZ, U.S.D.C. (W.D. Penn.):			
		<i>Covenant</i> , Civil Case No. 01-1997-DEZ, <i>Medrad, Inc. v. Tyco Healthcare Group LP, et al.</i> (August 11, 2003)			
		<i>Tyco Healthcare Group LP et al. v. Medrad, Inc., Civil Case No. 04-773, U.S.D.C. (S.D. Ohio):</i>			
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Examiner Signature		Date Considered	
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